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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,345	07/30/2001	Boris P. Belotserkovskii	A-69625-1/RFT/DLR	2746

7590 09/13/2004

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EXAMINER

LU, FRANK WEI MIN

ART UNIT PAPER NUMBER

1634

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,345	BELOTSERKOVSKII ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2004 and 14 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 36-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 36-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/1/2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on May 27, 2004 and oath or declaration filed on July 14, 2004 have been entered. The claims pending in this application are claims 1-8 and 36-41. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of applicant's amendment and arguments filed on May 27, 2004.

Claim Objections

2. Claim 1 is objected to because of the following informality: "with recombinase" should be "with a recombinase".

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-8 and 36-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Dayn (US Patent No. 5,929,043, published on July 27, 1999).

Dayn teaches recombinase mediated DNA therapies.

Regarding claims 1 and 2, since Dayn teaches a pair of single stranded probes having a complementary region wherein the pair of probes (two probes) is coated with a recombinase (see column 1, last paragraph and column 2) and claims 1 and 2 do not require that a first

Art Unit: 1634

recombinase is different from a second recombinase, Dayn discloses a first recombinase coated single stranded nucleic acid probe and a second recombinase coated single stranded nucleic acid probe which is substantially complementary to said first recombinase coated single stranded nucleic acid probe as recited in claims 1 and 2. Since Dayn teaches a target DNA sequence that has substantially homology with the probes wherein a proportion of the nucleotides of the target DNA sequence has modifications on various oxygens in the phosphate backbone or modifications on the ribose (see column 2) and the specification defines "analog probe" as "nucleic acids containing modifications to the natural-occurring phosphodiester linkages or modifications to the natural occurring ribose backbone" (see page 13, last paragraph), Dayn discloses an analog probe (ie., a target DNA sequence with the modifications on various oxygens in the phosphate backbone or modifications on the ribose) as recited in claim 1 wherein said analog probe has not been treated to coat it with a recombinase.

Regarding claims 3-6 and 36-39, since Dayn teaches that the probes are any sequences which have substantial homology with each other and with a target DNA sequence (see column 2, lines 27-35), Dayn discloses that said first single stranded nucleic acid probe is DNA as recited in claims 6 and 39. Since Dayn teaches that a target DNA sequence is tethered with some linking groups such as peptide nucleic acid chain (see column 3, third paragraph), Dayn discloses that said analog probe (ie., the target DNA sequence) comprises peptide nucleic acid as recited in claims 3 and 36. Since Dayn teaches that a target DNA sequence, in the most part, is the naturally occurring nucleotides although a proportion of the nucleotides is modified to enhance stability (see column 2, lines 36-58), Dayn discloses that said analog probe is a fusion sequence comprising nucleoside analogs (ie., peptide nucleic acid) and naturally occurring nucleosides as

recited in claims 4 and 37. Since, in the peptide nucleic acid chain taught by Dayn, the phosphates are substituted with glycine (see column 3, third paragraph), Dayn discloses that said nucleoside analog comprises at least one peptide nucleoside recited in claims 5 and 38.

Regarding claims 7, 8, 40, and 41, since Dayn teaches that the recombinase is recA from *E. coli* (see column 4, lines 3-31), Dayn discloses that said recombinase is a species of a prokaryotic recombinase wherein said prokaryotic recombinase is a recA recombinase as recited in claims 7, 8, 40, and 41.

Therefore, Dayn teaches all limitations recited in claims 1-8 and 36-41.

Response to Arguments

In page 6, first to fourth paragraphs of applicant's remarks, applicant argues that "[T]he Dayn reference neither teaches nor suggests every element of the rejected claims. Specifically, Dayn does not teach or suggest the combination of an analog probe and a first recombinase coated single stranded nucleic acid probe, wherein the analog probe has not been treated to coat it with recombinase, as recited in amended Claim 1. All of the single-stranded probes described in Dayn are required to be recombinase coated (see, e.g., column 1 last paragraph and column 2). The Dayn reference provides no motivation to combine an analog probe, wherein the analog probe has not been treated to coat it with recombinase, with a first recombinase coated single stranded nucleic acid probe, as recited in Claim 1".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection because, as shown in above rejection under 35 U.S.C 102, Dayn does teach the combination of an analog probe and a first recombinase coated single stranded nucleic

acid probe (one of pair of probes coated with a recombinase) wherein the analog probe (ie., the target DNA sequence taught by Dyan) has not been treated to coat it with a recombinase.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. No claim is allowed.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703)872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746.

The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
September 8, 2004


FRANK LU
PATENT EXAMINER